



IFW

Docket No.: 1056-0139PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Toshihiko NAITO et al.

Application No.: 10/577,308

Confirmation No.: @@@

Filed: April 28, 2006

Art Unit: N/A

For: UREA DERIVATIVE AND PROCESS FOR  
PREPARING THE SAME

Examiner: Not Yet Assigned

**LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450


Sir:

Attached is a copy of the English Translation of International Preliminary Report on Patentability (Chapter I). Please make this of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

Dated: OCT 3 2006

Respectfully submitted,

By 

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Attachment(s)

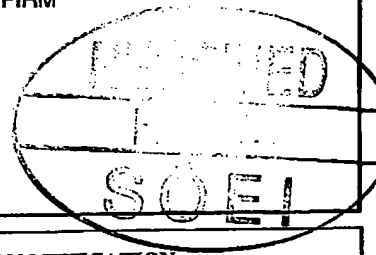
From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

HASEGAWA, Yoshiki  
SOEI PATENT AND LAW FIRM  
Ginza First Bldg.  
10-6, Ginza 1-chome  
Chuo-ku, Tokyo 104-0061  
JAPON



Date of mailing (day/month/year) 03 August 2006 (03.08.2006)		
Applicant's or agent's file reference EPC04-EE02 FP05-0115-DOWO-XX	IMPORTANT NOTIFICATION	
International application No. PCT/JP2004/016526	International filing date (day/month/year) 08 November 2004 (08.11.2004)	
Applicant EISAI CO., LTD. et al		

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

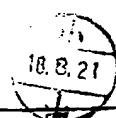
AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No. +41 22 338 82 70	Facsimile No. +41 22 338 82 70



## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference EPC04-EE02	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/JP2004/016526	International filing date ( <i>day/month/year</i> ) 08 November 2004 (08.11.2004)	Priority date ( <i>day/month/year</i> ) 11 November 2003 (11.11.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant EISAI CO., LTD.			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).
2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Box No. I  | Basis of the report   |
| <input type="checkbox"/> Box No. II            | Priority  |
| <input type="checkbox"/> Box No. III           | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV            | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> Box No. VI | Certain documents cited   |
| <input type="checkbox"/> Box No. VII           | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII          | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 338 82 70	Date of issuance of this report 27 July 2006 (27.07.2006)
	Authorized officer  Yoshiko Kuwahara  e-mail: pt07@wipo.int

## PATENT COOPERATION TREATY

TRANSLATION

PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference <b>EPC04-EE02</b>		Date of mailing (day/month/year)
		FOR FURTHER ACTION See paragraph 2 below
International application No. <b>PCT/JP2004/016526</b>	International filing date (day/month/year) <b>08.11.2004</b>	Priority date (day/month/year) <b>11.11.2003</b>
International Patent Classification (IPC) or both national classification and IPC		
Applicant <b>EISAI CO., LTD.</b>		

## 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

## 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

## 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016526

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ in written format
- ☐ in computer readable form
- c. time of filing/furnishing
- ☐ contained in the international application as filed.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2004/016526

**Box No. V** Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

**1. Statement**

Novelty (N)	Claims <u>1-17</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims _____	YES
	Claims <u>1-17</u>	NO
Industrial applicability (IA)	Claims <u>1-17</u>	YES
	Claims _____	NO

**2. Citations and explanations:****Documents listed in the international search report**

**Document 1:** WO 2002/32872 A1 (Eisai Co., Ltd.) 25 April 2002, Claims (particularly claim 11), Manufacturing Method 2-2 (p. 53); Manufacturing Example 4 (p. 116); Examples 368, 417, 619, 620 (p. 374, p. 400, p. 539, p. 540) & US 2004/53908 A1 & EP 1415987 A1

**Document 2:** GARDNER, g. ET AL., "In Vitro Activity of Sorghum-Selective Fluorophenyl Urea Herbicides," Pesticide Biochemistry and Physiology, 1985, Vol. 24, No. 3, p. 285-297

**Document 3:** NUGIEL, D. A. et al., "Synthesis and Evaluation of Indenopyrazoles as Cyclin-Dependent Kinase Inhibitors. 2. Probing the Indeno Ring Substituent Pattern," Journal of Medicinal Chemistry, 2002, Vol. 45, No. 24, p. 5224-5232

**(1) Claims 1-3 and 10-17**

Phenol derivative (a-12) is listed as a manufacturing intermediate of urea derivative compound (a-11) in document 1 (Manufacturing Method 2-2; Examples 368, 417, 619, 620, etc.)

In addition, document 2 describes phenol derivative compounds of N-cyclopropyl-N'-(2-fluoro-4-hydroxyphenyl) urea and the like, and because phenol derivative (a-12), which is an intermediate for obtaining the urea derivative compound (a-11) of Examples 619, 620, and the like is publicly known, this authority finds that persons skilled in the art can easily conceive of using a compound wherein the fluorine of the above compound is replaced by chlorine as an intermediate for obtaining the urea derivative compound (a-11) of Examples 368, 417, and the like.

Furthermore, Manufacturing Method 2-2 states that potassium carbonate can be used as a suitable base.

Therefore, based on the descriptions in documents 1 and 2, claims 1-3 and 10-17 lack an inventive step.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016526

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V.

## (2) Claims 4-9

Scheme 3 of document 3 describes a method for obtaining a urea compound wherein an amid compound is converted to an amine compound by an acid, reacted with phenyl chloroformate to obtain a carbamate, and then reacted with butyl amine.

As shown in (1) above, this authority finds that persons skilled in the art can easily conceive of using the method described in document 3 as a manufacturing method for N-cyclopropyl-N'-(2-chloro-4-hydroxyphenyl) urea, which is easily obtained based on the descriptions in documents 1 and 2. In addition, persons skilled in the art can easily obtain the carbamate derivative, which is an intermediate thereof.

Therefore, based on the descriptions in documents 1-3, claims 4-9 lack an inventive step.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/016526

## Box No. VI Certain documents cited

## 1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2004/101526 A1	25.11.2004	22.04.2004	22.04.2003

[E, X]

## 2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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